57

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 27 1988

Memorandum:

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: Results of the Laboratory Data Audit for the DPX-M6316 (Harmony) Validation on Wheat Grain and Straw.

From: Philip V. Errico, Section Head
Tolerance Petition Section III
Dietary Exposure Branch
Health Evaluation Division (TS-769C)

To: Elizabeth Leovey, Chemist
Quality Assurance Officer
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (TS-769C)

A data audit was performed on June 3,1988 on the method validation results for DPX-M6316 (Harmony) in wheat grain and straw. E.I. duPont de Nemours' methods AMR-646-86 and AMR-761-87 were used to analyze residues of DPX-M6316 in wheat grain and straw. Ronald F. Thomas was the chemist conducting the validation work in the Analytical Chemistry Laboratory (ACL), Chemical Operations Branch, Benefits Use Division. Dallas Wright is the ACL Quality Assurance Control Officer. The audit was performed by P. Errico, Dietary Exposure Branch (DEB nee RCB) accompanied by the OPP Quality Assurance Officer, E. Leovey. Jerry Stokes, also of DEB conducted a separate audit on the validation work for cyhalothrin. The results of this audit were previously submitted to E. Leovy (see memo by J. Stokes, June 27,1988).

The audit consisted of reviewing the laboratory file for DPX-M6316, interviewing the analyst, examining instrument log books, and conducting an exit interview. The audit questionnaire is presented as an attachment.

Examination of the method validation file shows the raw data base intact, the calculations were checked and found correct, and instruments, except for the HPLC and photoconductivity detector, all showed scheduled maintenance and use checks. The samples were injected into an HPLC instrument at the petitioner's

laboratory, and therefore the instrument log was not available for inspection. Upon interviewing the analyst, Ron Thomas, it was learned the actual injections, and instrument operation was performed by the petitioner. The analyst believed the instrument had been modified, but the actual parameters, extent of the modifications, and specifications of the instrument are unknown.

The performance of the method validation at ACL and the results were well documented. The only minor comments are as follows:

> The lowest value of the standard curve was 4 ng. This represented a fortification of 0.1 ppm. Validation of samples included fortifications of 0.05 ppm (2 ng).
>
> The point representing 20 ng on the standard curve was graphed at 21 ng. This error was not significant because the corrected standard curve verified the linear response, and calculated values were used to report recoveries.

Attachment: OPP Audit Questionaire
CC With Attachment: E. Leovy
CC Without Attachment: R.F., Circ., PP#6F3431, Harmony S.F., Errico